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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,012	07/03/2003	Karl Guegler	CL000968DIV2	6674

25748 7590 02/22/2006

CELERA GENOMICS
ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY
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ROCKVILLE, MD 20850

EXAMINER	
XIE, XIAOZHEN	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,012	GUEGLER ET AL.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 24-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 24-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1646, Examiner: Xiaozhen Xie.

Applicant's election of Group I, claim 3, in the reply filed on 29 December 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1, 2 and 4-23 have been cancelled. Claims 24-36 have been added. Claims 3 and 24-36 are pending and under examination.

Specification

The disclosure is objected to because of the following informalities:

The first line of the specification should include updated cross-reference to related applications.

The abstract of the disclosure is objected to because it does not describe the claimed invention. The claimed invention is directed to an isolated antibody that selectively binds to an ATP-dependent protease comprising the amino acid sequence of SEQ ID NO: 2, whereas abstract is directed to the polypeptide and polynucleotide encoding the polypeptide. Correction is required. See MPEP § 608.01(b).

Sequence Rules

The Instant application is not fully in compliance with 37CFR 1.821-1.825 for the following reasons: the sequences in the figures do not have sequence identifiers. See MPEP§2421.02(d);

> Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing " in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO: " in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.
>
> Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 26, 28-30, 32, 34 and 36 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are directed to an isolated antibody that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide comprises SEQ ID NO: 2. What applicant has described in the specification is an isolated antibody that

selectively binds to a polypeptide which has the amino acid sequence of SEQ ID NO: 2. Applicant has not provided adequate written description for antibodies that may bind flanking sequences of the polypeptide of SEQ ID NO: 2. There is no teaching what these sequences will be and how long these sequences will be. Thus, the claims encompass a genus of molecules, which vary substantially in composition, and could have very different structural and functional characteristics from the antibody that Applicant has disclosed.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making of the claimed product, or any combination thereof. In this case, there is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116). As discussed

above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of peptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that is part of the invention and reference to a method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated antibody that selectively binds to a polypeptide of SEQ ID NO: 2, but not the full scope of the claimed antibodies, is adequately described in the disclosure.

Claims 24, 26, 28-30, 32, 34 and 36 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody that selectively binds to a polypeptide consisting of SEQ ID NO: 2, does not reasonably provide enablement for antibodies that bind to a polypeptide comprising SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant claims are directed to an isolated antibody that selectively binds to a polypeptide, wherein the amino acid sequence of said polypeptide comprises SEQ ID NO: 2. The specification discloses an isolated antibody that selectively binds to a polypeptide consisting of SEQ ID NO: 2. The specification, however, does not teach how to make or use antibodies that bind to sequences that may flank SEQ ID NO: 2 in a polypeptide comprising SEQ ID NO: 2. Since the specification does not define what these sequences will be, one of skill in the art would evaluate all non-exemplified antibodies for binding activity. Thus, undue experimentation would be required for the artisan to make and use the invention as broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 3 and 24-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubenfield et al. (U. S. Patent No: 6,551,795 B1, which has a priority filing date on 18 February 1998). Rubenfield et al. disclose an antibody that selectively binds to a polypeptide which shares an epitope with the SEQ ID NO: 2 of the instant application (see attached alignment). Therefore, an antibody directed to this epitope is able to

selectively bind to a polypeptide of SEQ ID NO: 2. Rubenfield et al. teach that the antibody can be in the forms of monoclonal, polyclonal, and antigen binding fragments such as Fab' and F(ab'), and the antibody can be conjugated to a detectable label, and included in a composition comprising the antibody and a pharmaceutical acceptable carrier (specification [70] [72]). Therefore, claims 3 and 24-36 are anticipated by Rubenfield et al.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Xiaozhen Xie, Ph. D.
February 8, 2006

Query Match 1.6%; Score 14; DB 2; Length 810;
Best Local Similarity 100.0%; Pred. No. 0.0002;
Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 684 TLTGQLGDVMKESA 697
||||||||||||||
Db 631 TLTGQLGDVMKESA 644

RESULT 5
US-09-252-991A-30204
; Sequence 30204, Application US/09252991A
; Patent No. 6551795
; GENERAL INFORMATION:
; APPLICANT: Marc J. Rubenfield et al.
; TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES RELATING TO PSEUDOMONAS
; TITLE OF INVENTION: AERUGINOSA FOR DIAGNOSTICS AND THERAPEUTICS
; FILE REFERENCE: 107196.136
; CURRENT APPLICATION NUMBER: US/09/252,991A
; CURRENT FILING DATE: 1999-02-18
; PRIOR APPLICATION NUMBER: US 60/074,788
; PRIOR FILING DATE: 1998-02-18
; PRIOR APPLICATION NUMBER: US 60/094,190
; PRIOR FILING DATE: 1998-07-27
; NUMBER OF SEQ ID NOS: 33142
; SEQ ID NO 30204
; LENGTH: 820
; TYPE: PRT
; ORGANISM: Pseudomonas aeruginosa
US-09-252-991A-30204

Query Match 1.6%; Score 14; DB 2; Length 820;
Best Local Similarity 100.0%; Pred. No. 0.0002;
Matches 14; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 458 ALLEVLDPEQNHNF 471
||||||||||||||
Db 457 ALLEVLDPEQNHNF 470

RESULT 6
US-09-252-991A-29280
; Sequence 29280, Application US/09252991A
; Patent No. 6551795
; GENERAL INFORMATION:
; APPLICANT: Marc J. Rubenfield et al.
; TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES RELATING TO PSEUDOMONAS
; TITLE OF INVENTION: AERUGINOSA FOR DIAGNOSTICS AND THERAPEUTICS
; FILE REFERENCE: 107196.136
; CURRENT APPLICATION NUMBER: US/09/252,991A
; CURRENT FILING DATE: 1999-02-18
; PRIOR APPLICATION NUMBER: US 60/074,788
; PRIOR FILING DATE: 1998-02-18
; PRIOR APPLICATION NUMBER: US 60/094,190
; PRIOR FILING DATE: 1998-07-27
; NUMBER OF SEQ ID NOS: 33142
; SEQ ID NO 29280
; LENGTH: 809
; TYPE: PRT
; ORGANISM: Pseudomonas aeruginosa
; FEATURE:
; NAME/KEY: UNSURE
; LOCATION: (31)
; OTHER INFORMATION: Identity of amino acid at the above locations are unknown.
US-09-252-991A-29280

Query Match 1.5%; Score 13; DB 2; Length 809;
Best Local Similarity 100.0%; Pred. No. 0.0018;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 685 LTGQLGDVMKESA 697
|||||||||||||
Db 662 LTGQLGDVMKESA 674

RESULT 7
US-09-741-150-4
; Sequence 4, Application US/09741150
; Patent No. 6436689
; GENERAL INFORMATION:
; APPLICANT: GUEGLER, Karl et al
; TITLE OF INVENTION: ISOLATED HUMAN PROTEASE PROTEINS,
; TITLE OF INVENTION: NUCLEIC ACID MOLECULES ENCODING HUMAN PROTEASE PROTEINS, AND
; TITLE OF INVENTION: USES THEREOF
; FILE REFERENCE: CL000968
; CURRENT APPLICATION NUMBER: US/09/741,150
; CURRENT FILING DATE: 2000-12-21
; NUMBER OF SEQ ID NOS: 4
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 4
; LENGTH: 884
; TYPE: PRT
; ORGANISM: Human
US-09-741-150-4

Query Match 1.5%; Score 13; DB 2; Length 884;
Best Local Similarity 100.0%; Pred. No. 0.0019;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 371 LCFVGPPGVGKTS 383
|||||||||||||
Db 404 LCFVGPPGVGKTS 416

RESULT 8
US-10-160-187-4
; Sequence 4, Application US/10160187
; Patent No. 6620607
; GENERAL INFORMATION:
; APPLICANT: GUEGLER, Karl et al.
; TITLE OF INVENTION: ISOLATED HUMAN PROTEASE PROTEINS,
; TITLE OF INVENTION: NUCLEIC ACID MOLECULES ENCODING HUMAN PROTEASE PROTEINS, AND
; TITLE OF INVENTION: USES THEREOF
; FILE REFERENCE: CL000968DIV
; CURRENT APPLICATION NUMBER: US/10/160,187
; CURRENT FILING DATE: 2002-06-04
; PRIOR APPLICATION NUMBER: 60/252,410
; PRIOR FILING DATE: 2000-11-22
; PRIOR APPLICATION NUMBER: 09/741,150
; PRIOR FILING DATE: 2000-12-21
; NUMBER OF SEQ ID NOS: 4
; SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 4
; LENGTH: 884
; TYPE: PRT
; ORGANISM: Homo sapien
US-10-160-187-4

Query Match 1.5%; Score 13; DB 2; Length 884;
Best Local Similarity 100.0%; Pred. No. 0.0019;
Matches 13; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 371 LCFVGPPGVGKTS 383
|||||||||||||
Db 404 LCFVGPPGVGKTS 416

RESULT 9
US-09-248-796A-16773
; Sequence 16773, Application US/09248796A
; Patent No. 6747137
; GENERAL INFORMATION:
; APPLICANT: Keith Weinstock et al
; TITLE OF INVENTION: NUCLEIC ACID AND AMINO ACID SEQUENCES RELATING TO CANDIDA ALBI
; TITLE OF INVENTION: FOR DIAGNOSTICS AND THERAPEUTICS
; FILE REFERENCE: 107196.132